

2000

USP 24

THE UNITED STATES PHARMACOPEIA

NF 19

THE NATIONAL FORMULARY

*By authority of the United States Pharmacopeial  
Convention, Inc., meeting at Washington, D.C.,  
March 9-12, 1995. Prepared by the Committee of  
Revision and published by the Board of Trustees*

*Official from January 1, 2000*

UNITED STATES PHARMACOPEIAL CONVENTION, INC.  
12601 Twinbrook Parkway, Rockville, MD 20852

# DESCRIPTION AND SOLUBILITY

## Description and Relative Solubility of USP and NF Articles

The "description" and "solubility" statements pertaining to an article (formerly included in the individual monograph) are general in nature. The information is provided for those who use, prepare, and dispense drugs, solely to indicate descriptive and solubility properties of an article complying with monograph standards. The properties are not in themselves standards or tests for purity even though they may indirectly assist in the preliminary evaluation of the integrity of an article.

## Taste and Odor

Organoleptic characteristics are indicated in many instances because they may be useful and descriptive properties of substances. However, they are not meant to be applied as tests for identifying materials.

The inclusion of odor or taste among other descriptive properties may aid in identifying the causative agent following accidental exposure to or contact with a substance. This information is provided as a warning or to make an individual aware of sensations that may be encountered. The use of odor or taste as a test for identification or content is strongly discouraged.

The characteristic odor of a volatile substance becomes apparent immediately on opening a container of it. The odor may be agreeable (e.g., Peppermint Oil), unpleasant (e.g., Sulfur Dioxide), or potentially hazardous on prolonged exposure (e.g., Coal Tar). Moreover, an unexpected odor may be encountered if the characteristics of a substance are not known or if a container is incorrectly labeled. Consequently, containers of such substances should be opened cautiously, preferably in a well-ventilated fume hood. A characteristic taste or sensation produced in the oral cavity likewise is apparent if traces of residue materials on fingers are inadvertently brought into contact with the tongue or adjacent mucosal tissues.

## Solubility

Only where a special, quantitative solubility test is given in the individual monograph, and is designated by a test heading, is it a test for purity.

The approximate solubilities of Pharmacopeial and National Formulary substances are indicated by the descriptive terms in the accompanying table. The term "miscible" as used in this Pharmacopeia pertains to a substance that yields a homogeneous mixture when mixed in any proportion with the designated solvent.

Descriptive Term	Parts of Solvent Required for 1 Part of Solute
Very soluble	Less than 1
Freely soluble	From 1 to 10
Soluble	From 10 to 30
Sparingly soluble	From 30 to 100
Slightly soluble	From 100 to 1,000
Very slightly soluble	From 1,000 to 10,000
Practically insoluble, or Insoluble	10,000 and over

Soluble Pharmacopeial and National Formulary articles, when brought into solution, may show traces of physical impurities, such as minute fragments of filter paper, fibers, and other particulate

matter, unless limited or excluded by definite tests or other specifications in the individual monographs.

**Acacia:** Is practically odorless and produces a mucilaginous sensation on the tongue. Insoluble in alcohol. Optical rotation varies depending on the source of Acacia. For example, specific rotation values, calculated on the anhydrous basis and determined on a 1.0% (w/v) solution, usually are between  $-25^{\circ}$  and  $-35^{\circ}$  for *Acacia senegal* and between  $+35^{\circ}$  and  $+60^{\circ}$  for *Acacia seyal*. *NF category:* Emulsifying and/or solubilizing agent; suspending and/or viscosity-increasing agent; tablet binder.

**Acebutolol Hydrochloride:** White or almost white crystalline powder. Soluble in alcohol and in water; very slightly soluble in acetone and in methylene chloride; practically insoluble in ether. Melts at about  $141^{\circ}$  to  $144^{\circ}$ .

**Acetaminophen:** White, odorless, crystalline powder, having a slightly bitter taste. Soluble in boiling water and in 1 N sodium hydroxide; freely soluble in alcohol.

**Acetazolamide:** White to faintly yellowish white, crystalline, odorless powder. Very slightly soluble in water; sparingly soluble in practically boiling water; slightly soluble in alcohol.

**Acetic Acid:** Clear, colorless liquid, having a strong, characteristic odor, and a sharply acid taste. Specific gravity is about 1.045. Miscible with water, with alcohol, and with glycerin. *NF category:* Acidifying agent; buffering agent.

**Glacial Acetic Acid:** Clear, colorless liquid, having a pungent, characteristic odor and, when well diluted with water, an acid taste. Boils at about  $118^{\circ}$ . Specific gravity is about 1.05. Miscible with water, with alcohol, and with glycerin. *NF category:* Acidifying agent.

**Acetohexamide:** White, crystalline, practically odorless powder. Practically insoluble in water and in ether; soluble in pyridine and in dilute solutions of alkali hydroxides; slightly soluble in alcohol and in chloroform.

**Acetohydroxamic Acid:** White, slightly hygroscopic, crystalline powder. Melts, after drying at about  $80^{\circ}$  for 2 to 4 hours, at about  $88^{\circ}$ . Freely soluble in water and in alcohol; very slightly soluble in chloroform.

**Acetone:** Transparent, colorless, mobile, volatile liquid, having a characteristic odor. A solution (1 in 2) is neutral to litmus. Miscible with water, with alcohol, with ether, with chloroform, and with most volatile oils. *NF category:* Solvent.

**Acetylcholine Chloride:** White or off-white crystals or crystalline powder. Very soluble in water; freely soluble in alcohol; insoluble in ether. Is decomposed by hot water and by alkalis.

**Acetylcysteine:** White, crystalline powder, having a slight acetic odor. Freely soluble in water and in alcohol; practically insoluble in chloroform and in ether.

**Acetyltributyl Citrate:** Clear, practically colorless, oily liquid. Insoluble in water, freely soluble in alcohol, in isopropyl alcohol, in acetone, and in toluene. *NF category:* Plasticizer.

**Acetyltriethyl Citrate:** Clear, practically colorless, oily liquid. Insoluble in water, freely soluble in alcohol, in isopropyl alcohol, in acetone, and in toluene. *NF category:* Plasticizer.

**Acyclovir:** White to off-white, crystalline powder. Melts at temperatures higher than  $250^{\circ}$ , with decomposition. Slightly soluble in water; soluble in 0.1 N hydrochloric acid; insoluble in alcohol.

**Adenine:** White crystals or crystalline powder. Is odorless and tasteless. Very slightly soluble in water; sparingly soluble in boiling water; slightly soluble in alcohol; practically insoluble in ether and in chloroform.